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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,950	03/07/2002	Sophie Gaubert	02043	2908

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
05/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/069,950	GAUBERT ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,21-33 and 35-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19, 21-33 and 35-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 3-23-07 is acknowledged.

Claims included in the prosecution are 16-19, 21-33 and 35-65.

Upon consideration, the 102 rejection over Haan et al is withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The parent claim 18 is drawn to the production of antibodies; claim 38 recites the same limitation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 16-17, 21-31 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Barenholz et al (6,156,337).

According to instant claims the vesicles are multilamellar with an onion structures having an internal liquid crystal structure formed by a stack of concentric bilayers based on amphiphilic agents alternating with layers of water. The surfactant is a phospholipid and the co surfactant is cholesterol.

Barenholz et al discloses a method of preparation of multilamellar vesicles using phospholipids, which are in liquid crystalline state and cholesterol. The vesicles contain antigens for vaccination. The method of administration is either by oral or buccal, rectal or pulmonary routes. Nasal administration is implicit in 'pulmonary route' taught by Barenholz. The composition further contain lipid A (immuno-modulating substance (col. 7, lines 50-55; col. 8, line 46 through col. 10, line 27 and Examples). The reference meets the requirements of instant claims.

The 102 (b) rejection will be reconsidered when the English translation of the priority papers are provided.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16-19, 21-33 and 35-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenholz et al (6,156,337) or Brownlie et al (Microbial Pathogenesis, 1993) of record in combination with FR 2769022 also of record or vice versa.

As pointed out above, according to instant claims the vesicles are multilamellar with an onion structures having an internal liquid crystal structure formed by a stack of concentric bilayers based on amphiphilic agents alternating with layers of water. The surfactant is a phospholipid and the co surfactant is cholesterol.

Barenholz et al discloses a method of preparation of multilamellar vesicles using phospholipids, which are in liquid crystalline state and cholesterol. The vesicles contain antigens for vaccination. The method of administration is either by oral or buccal, rectal, injection or pulmonary routes. (col. 8, line 46 through col. 10, line 27 and Examples). The method of preparation appears to be similar to instant method of preparation (Method E in Fig. 3).

Brownlie et al disclose multilamellar vesicles incorporating an antigen suitable for nasal and oral administration (abstract, Materials and Methods).

FR. Teaches vesicles having the same structure as in instant invention and the use of these vesicles for parental vaccination (abstract and examples).

Assuming that the vesicles taught by Barenholz and Brownlie et al are different from instant vesicles, the use of the vesicles of FR instead of the vesicles of Barenholz or Brownlie would have been obvious to one of ordinary skill in the art since they are similar vesicles. Alternately, the use of nasal or oral route of administration instead of parenteral administration taught by Fr would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since Barenholz teaches that the vesicular vaccines can be administered either by injection or by oral, buccal or pulmonary routes and Brownlie teaches that vesicular antigen preparations can be administered by intranasal route.

7. Claims 16-17 and 21-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenholz cited above in combination with Roux (5,908,697) or vice versa.

Barenholz et al discloses a method of preparation of multilamellar vesicles using phospholipids, which are in liquid crystalline state and cholesterol. The vesicles contain antigens for vaccination. The method of administration is either by oral or buccal, rectal, injection or pulmonary routes. (col. 8, line 46 through col. 10, line 27 and Examples). The method of preparation appears to be similar to instant method of preparation (Method E in Fig. 3).

As also discussed before, Roux discloses active principle carriers containing lecithin (phospholipid) and sucrose ester and the other surfactants. The structures disclosed by Roux are multilamellar vesicles with an onion like structure having an internal liquid crystal structure formed by a stack of concentric bilayers. According to

Roux, these vesicles have certain advantages, which include less sensitivity to bacterial contamination. The vesicles have diameters of 0.1 and 50 microns. The two surfactants according to Roux have HLB values between 3 and 7 and 8-15 respectively (abstract, col. 3, lines 4-27; col. 5, line 40 through col. 7, line 40; Examples and claims). What are lacking in Roux are the teachings of using an antigen as active principle and mucosal administration of the composition to elicit an immune response.

Assuming that Barenholz's multilamellar liposomes are different from instant liposomes, to use multi-lamellar liposomes containing lecithin and sucrose esters of Roux would have been obvious to one of ordinary skill in the art because of the advantages taught by Roux. Alternately, the use of antigen as the active principle and administer the composition of Roux mucosally, with a reasonable expectation of success, since the reference of Barenholz teaches antigens can be administered orally, buccally and by pulmonary routes.

8. Claims 18-19 and 36-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenholz et al (6,156,337) or Brownlie et al (Microbial Pathogenesis, 1993) of record in combination with FR 2769022 also of record or vice versa as set forth above, in further combination with combination with Doerschuk (5,702, 946).

The teachings of Barenholz, Brownlie and FR have been discussed above. What Is lacking Barenholz and Brownlie is the purification of the immunoglobulins. It is unclear whether FR teaches purification of the immunoglobulins.

The reference of Doerschuk teaches the conventional techniques of purifying the immunoglobulins col. 9, lines 25-30; col. 14, line 50).

The purification of the antibodies produced by the administration of the antigen containing multilamellar vesicles would have been obvious to one of ordinary skill in the art since purification of antibodies by conventional methods is known in the art as evident from Doerschuk.

9. Claims 18-19 and 36-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barenholz cited above in combination with Roux (5,908,697) or vice versa as set forth above, further in view of Doerschuk (5,702,946).

The teachings of Barenholz and Roux have been discussed above. What is lacking in these references is the purification of immunoglobulins.

The reference of Doerschuk teaches the conventional techniques of purifying the immunoglobulins col. 9, lines 25-30; col. 14, line 50).

The purification of the antibodies produced by the administration of the antigen containing multilamellar vesicles would have been obvious to one of ordinary skill in the art since purification of antibodies by conventional methods is known in the art as evident from Doerschuk.

Applicant's arguments and declarations have been fully considered, but are deemed to be moot in view of the new rejections.

The examiner requests an English translation of FR 2769022 if one is readily available.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK